UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

MOBILE MEDICAL INTERNATIONAL

CORPORATION,

Plaintiff,

v. : Case No. 2:07-cv-231

:

ADVANCED MOBILE HOSPITAL SYSTEMS, INC., TRACTUS MEDICAL, INC., and JOHN DOES 1-10,

:

Defendants.

OPINION AND ORDER

Plaintiff Mobile Medical International Corporation ("MMIC") seeks a declaratory judgment with respect to the validity and non-infringement of U.S. Patent No. 4,915,435 (the "'435 Patent" or "patent"). Defendants Advanced Mobile Hospital Systems, Inc. and Tractus Medical, Inc. (collectively "AMOHS") have counterclaimed for patent infringement. Tractus is a subsidiary of AMOHS and the alleged owner of the '435 Patent. Now before the Court are MMIC's motions for summary judgment asserting non-infringement and invalidity, and AMOHS's motions to strike portions of MMIC's summary judgment filings.

For the reasons set forth below, those motions are denied.

I. Factual Background

The '435 Patent describes a transportable unit in which invasive surgical procedures can be performed. Both AMoHS and MMIC have manufactured and sold or leased mobile operating room

units. MMIC was a licensee of the `435 Patent through 2003.

AMOHS contends that twelve of MMIC's Mobile Surgical Units

("MSUs") manufactured since 2003 infringed the `435 Patent. The patent expired in 2012.

The '435 Patent was filed on April 4, 1989 and issued shortly thereafter to Dr. Brian Levine. Claim 1 of the patent, which is arguably the broadest of the patent's claims, set forth the basic elements of the unit:

1. A mobile invasive surgery van capable of being transported on the roads and highways equipped with essential equipment for invasive surgery to be performed within the van, said van comprising:

a main body section that is capable of being towed, mounted on wheels for mobility by a separate power section;

an expandable portion of said main body provided by telescoping side sections thereof which move outwardly from the main body portion in order to form an expanded invasive surgery room;

an operating table centrally located in said expandable section, said table being stowable so that the expandable section may be nested or expanded without removal of said surgery room operating table from said van.

ECF No. 149-3 at 9.

Dr. Levine acknowledged in his patent application that mobile medical vehicles had already been designed, but characterized them as either "diagnostic" or "therapeutic." Id. at 5. According to Dr. Levine, invasive surgical procedures were never performed in those pre-patent units, and AMOHS contests

whether invasive surgery was ever approved. While MMIC contends that Dr. Levine failed to adequately disclose the structures of those pre-existing medical vehicles, AMoHS counters that the United States Patent and Trademark Office ("PTO") examiners were fully aware of the vehicles and their respective structures.

MMIC claims that the patent is invalid because "[i]n reality, Levine invented nothing." ECF No. 149-1 at 6. In support, MMIC cites long-existing entities such as mobile army surgical hospitals ("MASH" units), as well as prior publications. An example of the latter is a 1940 publication from a British medical journal showing a self-contained "mobile operating theatre" for performing sterile operations in "outlying districts." ECF No. 149-7. In 1968, a printed publication from the Journal of the American Medical Association showed a "hospital on wheels" designed to "treat patients on the spot." ECF No. 149-8. That publication suggested an interior that could accommodate complex surgeries, including heart surgery. In 1981, a publication called International Hospital Equipment advertized a "SITEC" mobile surgical unit that included a semi-tractor and trailer with three rooms: an anaesthetic and recovery area, an operating room, and a room for scrubbing and sterilization.

In 1982, European Patent Application 0 065 398 ("EP '398") disclosed a trailer with telescoping sides, an operating table, beds, sinks, and other equipment that remained in the trailer

when the telescoping sides either slid outward or nested inward. Another patent application ("US '705"), filed in the United States more than one year before the '435 application, showed a container with surgical equipment that could be relocated by a truck or other form of transportation.

A 1984 article by Oded D. Gasko depicted expandable trucks and relocatable shelters for mobile surgery that were actually used in Lebanon prior to the '435 Patent application. In January 1988, Linda O. Stone published "Mobile Unit Lithotripsy," which disclosed an expandable trailer equipped with powered telescoping sides. The Stone publication identified the expanded portion as an "operating room." ECF No. 150-15. Also prior to 1989, Calumet Coach designed, built, and sold expandable semi-trailers equipped with an operating table and surgical equipment.

Given these prior publications, it is undisputed that more than one year prior to the '435 application in April 1989 persons of ordinary skill in the art knew about telescoping trailers capable of being equipped with surgical equipment. Such persons would also have been aware of rolling instrument tables, autoclaves, surgical monitors, patient lifts, and surgeon scrub rooms that could be used in mobile units.

However, AMoHS disputes whether the equipment depicted in any prior art met the definition of essential equipment for invasive surgery set forth in this Court's Markman ruling. The

Court has defined the '435 Patent as requiring "all the essential requirements for invasive surgery that a permanent and fixed hospital facility has" including "equipment required by health, building, and other regulatory codes for invasive surgery at the time and place of the intended use." ECF No. 112 at 6-8. AMOHS contends that according to MMIC's expert, Anthony Brummel, there was no prior art in 1989 depicting a unit with such equipment.

Mr. Brummel's deposition testimony included the following exchange:

Q: Okay, And can you name a single mobile unit prior to 1989 that met all the requirements that a fixed hospital facility's operating room would have had in the United States?

A: No.

Q: It didn't exist?

A: No.

. . .

Q: So, you can't name a piece of published prior art before 1989 that supplies this element of being equipped with essential equipment for invasive surgery. Is that correct?

A: I cannot provide that.

Q: Let me make it simple for you. Is there a single piece of prior art that you identified in your report that contained all the essential equipment for invasive surgery required by codes and regulations?

A: No.

Q: So none of the prior art that you referenced alone anticipated the Levine patent, right?

A: No.

ECF No. 185-1 at 21-22. Relying in part upon this testimony, AMoHS contends that genuine issues of material fact preclude summary judgment on the question of the patent's validity.

In addition to its claim of patent invalidity, MMIC asserts that it has not infringed the '435 Patent. MMIC's primary argument with respect to non-infringement is that its mobile units are used as adjuncts to fixed hospitals, and are not selfcontained surgical centers. MMIC submits that the units are only outfitted with surgical equipment once they are attached to the hospital, and that such equipment is typically provided by the client. This client-provided equipment would allegedly include an operating table. MMIC also submits that its units allowed customers to position an operating table as desired; did not have tie-downs to store operating tables or other surgical equipment; required an external power source; and did not contain changing areas, male and female toilets, lockers, showers, patient lifts or elevators, a waiting room with public restroom, telephone, or drinking water, or food preparation supplies - each of which are commonly required by health, building, and other regulatory codes for invasive surgery.

AMOHS argues that many of these facts are immaterial to the motion for summary judgment, as the patent does not require them.

AMOHS further asserts that no regulations in the United States,

Oman, Saudi Arabia or Iraq required equipment for mobile invasive surgery to include separate bathrooms, lockers, showers, elevators, waiting rooms, food preparation and the like. AMOHS again derives primary support for its position from the deposition testimony of MMIC's expert, Mr. Brummel.

MMIC filed this lawsuit on October 30, 2007, and AMOHS and Tractus responded with an answer and counterclaim. On February 25, 2008 and March 29, 2009, MMIC filed requests for reexamination of the '435 patent with the PTO. The instant litigation was stayed on August 27, 2008 pending the outcome of the reexaminations. During the first reexamination, the PTO rejected claims 19-25 and 31-35 of the '435 Patent as unpatentable, and the patentee canceled those claims. During the second reexamination, the PTO examiner rejected the remaining claims. That decision was reversed by the Board of Patent Appeals and Interferences, which found claims 1-18 and 30 valid in view of the prior art asserted.

II. Motions to Strike

Before addressing MMIC's summary judgment motions, the Court must rule upon AMoHS's motions to strike MMIC's statement of undisputed facts ("SUF"). ECF Nos. 165, 188. In support of its two summary judgment motions, MMIC filed a single SUF. ECF No. 149-16. The SUF is divided into three sections: first, a section entitled "The '435 Patent'" which sets forth facts most relevant

to the issue of invalidity; second, a section entitled "Prior Art and The Level of Ordinary Skill Prior to 1989" which again pertains to invalidity; and third, a section entitled "MMIC's Accused Surgery Units" offering facts relevant to the question of non-infringement. AMOHS complains that the SUF does not identify which facts are material, is not cited in the motions for summary judgment, and is neither "separate" nor "concise" as required by Local Rule 56(a).

This Court's Local Rule 56 requires that "[a]ny motion for summary judgment . . . must be accompanied by a separate and concise statement of undisputed facts." L.R. 56(a). Federal Rule of Civil Procedure 56(c) requires that supporting factual positions cite to relevant materials in the record. MMIC complied with both the local and federal requirements, having submitted a Rule 56 statement of undisputed facts with supporting record citations. While it would have been better practice for MMIC to have filed a distinct statement of undisputed facts for each summary judgment motion, the relationship between the various sections of the SUF and the two summary judgment motions is sufficiently clear. The motions to strike are denied.

¹ AMoHS has also asserted a series of objections to MMIC's evidence, arguing insufficient personal knowledge and evidentiary failings, including hearsay. ECF No. 185 at 2-3. Because the Court is denying MMIC's motions for summary judgment, the objections are moot for present purposes but may be reasserted at a future date.

III. Summary Judgment

A. Legal Standard

The Court next turns to MMIC's two pending motions for summary judgment. The Court applies the same summary judgment standard to patent questions as it does to other types of claims. See Desper Products, Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1332 (Fed. Cir. 1998); Becton Dickinson & Co. v. C.R. Bard. Inc., 922 F.2d 792, 795-96 (Fed. Cir. 1990); Alloc, Inc. v. Norman D. Lifton Co., 653 F. Supp. 2d 469, 473 (S.D.N.Y. 2009). When deciding issues in a patent case, a district court applies the law of the Circuit in which it sits to non-patent issues, and the law of the Federal Circuit to issues of substantive patent law. See In re Cambridge Biotech Corp., 186 F.3d 1356, 1368 (Fed. Cir. 1999).

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In ruling on a motion for summary judgment, the Court must view all evidence in the light most favorable to the nonmoving party, Overton v. N.Y. State Div. of Military & Naval

Affairs, 373 F.3d 83, 89 (2d Cir. 2004), and "resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought," Sec Ins. Co. of Hartford v. Old Dominion Freight Line Inc., 391 F.3d 77, 83 (2d Cir. 2004).

B. Non-Infringement

MMIC first moves for summary judgment on its claim of non-infringement. ECF No. 149. MMIC submits that if the Court finds non-infringement, it need not proceed to the question of the patent's validity.

Summary judgment of non-infringement is proper if "no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." Gart v. Logitech, Inc., 254 F.3d 1334, 1339 (Fed. Cir. 2001). The patent owner, which in this case is the non-movant AMOHS, has the ultimate burden to prove infringement. Medtronic, Inc. v. Mirowski Family Ventures, LLC, 134 S. Ct. 843, 849 (2014). MMIC, in moving for summary judgment, bears the initial burden of either "providing evidence that would preclude a finding of infringement" or "showing that the evidence on file fails to establish a material issue of fact essential to [AMOHS's] case." Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1046 (Fed. Cir. 2001). If MMIC can carry that burden, the question at summary judgment turns to whether a reasonable

jury could find evidence sufficient to support AMoHS's burden of proof. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986).

A patent infringement analysis involves two steps. First, the court determines the scope and meaning of the patent claims asserted. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) ("[T]he interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law, exclusively for the court."). As noted above, this Court previously issued a Markman ruling construing the patent's terms. In the second step, the accused product, method, or process is compared to the properly-construed claims. See CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1365 (Fed. Cir. 2002); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). This second step is the focus of MMIC's non-infringement motion.

MMIC's primary argument with respect to non-infringement is that its mobile units are not self-contained mobile surgical centers, and must instead be attached to a fixed structure such as a hospital. In opposition to the summary judgment motion, AMOHS references MMIC marketing materials proclaiming that the MSU is, in fact, the "[w]orld's first fully self-contained, sterile, operating room and patient care facility . . . which is

mobile." ECF No. 169-3 at 49. Furthermore, while MMIC claims that its units were not designed to stand alone and required power from another source, the same marketing document listed "[r]edundant systems for power" and an "Integrated power and Generator Set." Id. at 49, 51. AMoHS also contends that even when the MSUs were not sold fully equipped, MMIC assisted customers with setting up infringing units. Finally, AMoHS submits that the '435 Patent does not require an entirely self-contained, deployable mobile unit.

Citing the Court's Markman ruling, MMIC's next argument is that its units did not include all of the equipment required by applicable regulatory codes. MMIC also notes that those codes can vary from one locale to another, and from one time period to another. Given such variations, MMIC asserts that AMOHS cannot show infringement because it cannot prove that the MSUs met the codes in each of the jurisdictions where the units were leased or sold.

AMOHS responds that the only relevant codes were those governing invasive surgery, and that codes requiring elevators or food services are inapplicable to a mobile unit. AMOHS has also offered a detailed affidavit from William Waugh, former Chief Operating Officer of MMIC and currently a consultant with AMOHS. Mr. Waugh opines that based upon his experience, "the MMIC MSUs necessarily were equipped with the equipment required by health,

building and other regulatory codes for invasive surgery anywhere in the U.S. during the time frame from January 2003 until January 2013." ECF No. 169-5 at 9.

Further, MMIC has claimed in marketing materials that its units met the applicable codes. In a slide deck document prepared by MMIC in 2007, the company asserted that its MSUs met the "standard of care" through compliance with, among other things: state licensure; life safety codes; NFPA fire protection requirements; AIA standards for mobile health care facilities; and national plumbing codes. ECF 169-4 at 35. AMOHS therefore argues that there are genuine issues of material fact with regard to both the way in which the MSUs are equipped, and the extent to which they met the relevant codes.

Viewing these facts in a light most favorable to AMoHS, the Court finds that MMIC is not entitled to summary judgment on the question of non-infringement. MMIC's own materials, produced in the course of discovery, call into question its claims that the MSU's (1) were not self-contained and mobile, and (2) did not satisfy the relevant codes as defined in the Court's Markman ruling. See, e.g., TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1261-62 (Fed. Cir. 2008) (party's admissions created genuine issue of material fact regarding non-infringement). AMoHS's expert, equipped with both years of experience in the industry and familiarity with the MSUs at issue, has also suggested that

the MMIC units satisfy the *Markman* definition of essential equipment for invasive surgery. Accordingly, the motion for summary judgment of non-infringement is **denied**.

C. Invalidity

Having determined that summary judgment is not warranted on the basis of non-infringement, the Court next considers MMIC's motion for summary judgment of invalidity. ECF No. 150. The '435 Patent was recently reexamined by the PTO, and is presumed valid. See Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1323 (Fed. Cir. 2004). Overcoming that presumption requires clear and convincing evidence. 35 U.S.C. § 282; Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (2011).

MMIC argues that Dr. Levine did not invent the mobile surgical unit, but instead borrowed from prior art such as the articles and patent applications discussed previously. Indeed, specific characteristics of the MSUs, including telescoping side sections, were described in prior art. MMIC therefore submits that the '435 Patent was both anticipated and obvious, and is thus invalid.

Patent anticipation requires a showing that a prior art reference is "identical in all material respects" to the claimed invention. Door-Master Corp. v. Yorktowne, Inc., 256 F.3d 1308, 1312 (Fed. Cir. 2001) (quoting Hupp v. Siroflex of Am., Inc., 122 F.3d 1456, 1461 (Fed. Cir. 1997)). Anticipation is a question of

fact. Int'l Seaway Trading Corp. v. Walgreens Corp., 589 F.3d 1233, 1237 (Fed. Cir. 2009). To show obviousness, the alleged infringer must demonstrate that the differences between the claims and the prior art are such that "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2006). Obviousness is ultimately a conclusion of law premised on underlying findings of fact, including the scope and content of the prior art, the differences between the claimed invention and the prior art, the level of ordinary skill in the pertinent art, and secondary considerations of non-obviousness.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007); Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

MMIC notes that before applying for the '435 Patent, Dr. Levine worked with mobile lithotripter trailers.² Depictions of the lithotriptor unit (ECF No. 150-14) and Dr Levine's mobile operating room (ECF No. 150-18) are quite similar, including their shapes, room locations, bed placements, and exit points.

MMIC also cites EP '398, which depicted a medical trailer with expandable side sections. MMIC contends that both of these designs anticipated the '435 Patent.

While the prior art identified by MMIC certainly depicted

 $^{^{2}\}text{Lithotripters}$ use ultrasound waves to break up kidney stones in the body.

similar designs, a reasonable jury could conclude that the prior art was not "identical in all material respects." Door-Master Corp., 256 F.3d at 1312. With respect to the lithotriptor trailers, the parties clearly dispute whether lithotripsy is equivalent to invasive surgery, with Dr. Levine testifying that it does not require the same sort of sterile environment. ECF No. 186-4 at 3-4. The parties also dispute whether any prior art depicted trailers equipped for surgery with a stowed operating table. Moreover, in the deposition testimony cited above, Mr. Brummel admitted that he was unable to produce any prior art that anticipated the '435 Patent. Accordingly, and viewing the facts in a light most favorable to the non-movant, MMIC has failed to demonstrate through clear and convincing undisputed facts that the patent was anticipated and is therefore invalid.

MMIC also submits that the features described in the '435 Patent would have been obvious to anyone seeking to assemble a mobile surgical unit, and that equipping such a unit would have merely been a matter of borrowing from past designs and following the relevant codes for invasive surgery. AMOHS draws a distinction between assembling a mobile surgical unit and having the insight to invent such a unit in the first place. AMOHS also argues that MMIC's position suffers from hindsight bias, as obviousness "cannot be based on the hindsight combination of components selectively culled from the prior art to fit the

parameters of the patented invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998).

When asked about hindsight bias, Mr. Brummel arguably conceded that his analysis did not account for such bias:

- Q: Mr. Brummel, did you do anything to avoid hindsight bias in your work?
- A: Define hindsight bias, please.
- Q: Where you might have a temptation to read into the prior art the teachings of the Levine patent.
- A: I don't believe so.

(Doc. 186 ex. A) Brummel Dep. at 123-24. When this testimony is viewed in a light most favorable to AMoHS, a reasonable jury could discount Brummel's opinion with respect to obviousness.

See, e.g., ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1327 (Fed. Cir. 2012) ("[T]he expert's testimony on obviousness was essentially a conclusory statement that a person of ordinary skill in the art would have known, based on the 'modular' nature of the claimed components, how to combine any of a number of references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.").

In order to counter the possible influence of hindsight, courts have identified "essential components" of the obviousness analysis:

Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the

claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). These objective considerations can protect against the prejudice of hindsight bias, which often overlooks that "[t]he genius of invention is often a combination of known elements which in hindsight seems preordained." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001).

Power Integrations, Inc. v. Fairchild Semiconductor Int'1, Inc., 711 F.3d 1348, 1368 (Fed. Cir. 2013). Here, AMoHS offers several considerations that, it claims, should have been addressed in order to eliminate hindsight bias. For example, according to MMIC's Rule 30(b)(6) deponent, company President Rick Cochran, it took MMIC fifteen years to develop its mobile medical unit and introduce it to the market in 1994. ECF No. 186-5 at 3-5. When introduced, the product was said to be the first of its kind. Id. at 3-4. Cochran further testified that MMIC was fulfilling an unmet need for a mobile surgical center. Given the considerable period of time devoted to development (1979 to 1994), and the alleged uniqueness of the product, a reasonable jury could conclude that the '435 Patent was not obvious at the time of Dr. Levine's 1989 application and was not anticipated by the prior art.

The record also reflects industry skepticism prior to the '435 Patent. In the Rule 30(b)(6) deposition, Cochran related a story about an individual with experience in the industry ridiculing the concept of the MSU: "I remember being at an

ambulatory meeting and Bob Marasco, who worked with most of the guys in the industry that did their first surgery centers, you know, stood up and laughed and said, Rick, like you'll ever be doing surgery in the back of a truck." ECF No. 186-6 at 33.

Such a response, when viewed in a light most favorable to AMOHS, could further support a reasonable jury's conclusion that the '435 Patent was not obvious at the time of the application.

AMOHS cites other factors, such as the lack of applicable regulations and MMIC's licensing of the '435 Patent, as secondary factors for consideration.

With respect to differences between the prior art and the '435 Patent, AMoHS highlights the same prior art cited by MMIC in support of its arguments regarding anticipation and obviousness. For example, AMoHS submits that the cited European patent application, EP '398, did not meet the codes for invasive surgery. The cited United States patent, US '705, was not self-contained, and instead consisted of canister-like containers that required equipment from other containers. The "SITEC" unit described in 1981 did not have expandable sides. And the Calumet Coach field hospitals had fold-out rather than telescoping sides.

At trial, experts may explain to the jury the significance of such differences. On the present record, however, and again viewing the facts in light most favorable to AMOHS, a reasonable jury could find that MMIC has failed to carry its burden with

respect to the question of invalidity.

IV. Conclusion

For the reasons set forth above, MMIC's motions for summary judgment (ECF Nos. 149, 150) and AMoHS's motions to strike (ECF Nos. 165, 188) are **denied**.

Jury selection is scheduled for Monday, June 13, 2016 at 1:00 p.m. with trial to commence thereafter. A pretrial conference is scheduled for Monday, May 16, 2016 at 11:30 a.m.

DATED at Burlington, Vermont, this 29^{th} day of October, 2015.

/s/ William K. Sessions III
William K. Sessions III
District Court Judge